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| 10/817,423 | 04/02/2004 | Thomas R. Scott | CXU-407 | 1563 |

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| EXAMINER | |
|---|---|
| HADDAD, MAHER M | |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1644 | |

DATE MAILED: 08/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/817,423 | SCOTT ET AL. | |
| | Examiner | Art Unit | |
| | Maher M. Haddad | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on 5/18/05.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 15-21 and 43-56 is/are pending in the application.

4a) Of the above claim(s) 50,53 and 56 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 15-21,43-49,51,52,54 and 55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/15/05
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 15-21 and 43-56 are pending.

2. Applicant's election of Group II, claims 15-21 (now claims 15-21, 43-49, 51-52, and 54-55) directed to a therapeutic composition comprising a polypeptide capable of binding to at least one of α6β1 integrin receptor and α6β4 integrin receptor and IL-2 as the species in the reply filed on 2/3/05 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The search is extended to cover all the second components species cited in claim 18.

3. Claim 50, 53 and 56 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to a nonelected species.

4. Claims 15-21, 43-49, 51-52, and 54-55 are under examination as they read on a therapeutic composition comprising a polypeptide capable of binding to at least one of α6β1 integrin receptor and α6β4 integrin receptor and a second component.

5. Applicant's IDS, filed 7/15/04, is acknowledged.

6. The specification is objected to for failing to provide a brief description of each individual Figure. Figure 6-9 each individual figure must be separately described. Correction is required.

7. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed.*

In addition, Applicant should avoid the use of novel in the title, as patents are presumed to be novel and unobvious.

8. The specification is objected to for the following informalities: the "anti-x 6 antibody" disclosed on page 31, line 14 is misspelled. Correction is required.

9. Claim 15 is objected to because it is improper to refer to α6β1 integrin "receptors" and α6β4 integrin "receptors". It is suggested that the claim recites the singular form. Correction is required.

10. Claim 18 is objected to because it is missing a period at the end of the claim.

11. The following is a quotation of the second paragraph of 35 U.S.C. 112.

*The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.*

12. Claims 18, 48-52 and 54-55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claim 18 is indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of ..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 706.03(Y).

B. The recitation "specifically binds" recited in claims 48 (line 5), 51 (line 5) and 54 (line 5) is ambiguous. It unclear whether the first component or the integrin receptor that "specifically binds" to the polypeptide.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:
*The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.*

14. Claims 15-21, 43-49, 51-52, and 54-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification does not reasonably provide **enablement** for a therapeutic agent comprising a fused or chimeric polypeptide "comprising" a fused or chimeric polypeptide comprising a first component "comprising" a polypeptide that specifically binds to a least one of α6β1 integrin receptor and α6β4 integrin receptor, wherein the polypeptide "comprises" the "G3 subdomain of the laminin-5 α3 chain" or a "fragment, mutant , homolog, ortholog, analog, or allele thereof" and a second component chemically bound to said first component wherein said second component comprises an "agent" for use in the destruction of or neutralization of a pathogen comprising an least one of α6β1 integrin receptors and α6β4 integrin receptors on the surface of the pathogen in claim 15 , wherein the second component is any polypeptide in claim 16, wherein the first component comprises at "least about 70% sequence identity" with SEQ ID NO: 2, 4 or 6, in claims 19-21 or at "least about 90% sequence identity" with SEQ ID NO: 2, 4 or 6, in claims 43-45 or wherein the first component "comprises" a segment consisting of SEQ ID NO: 6 in claim 47; a fused or chimeric polypeptide comprising a first component "comprising" a polypeptide, wherein the polypeptide "comprises" at "least a segment of the G-domain of a laminin-5 α3 chain" and the polypeptide specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor that specifically binds to a polypeptide comprising a

segment consisting of SEQ ID NO:2, 4, or 6 and any "second component" chemically bond to said first component in claims 48, 51, and 54, wherein the second component is a polypeptide in claims 49, 52, and 55 . The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and or use the invention commensurate in scope with this claim.

The specification disclosure does not enable one skilled in the art to practice the invention without an undue amount of experimentation.

Factors to be considered in determining whether undue experimentation is required to practice the claimed invention are summarized *In re Wands* (858 F2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)). The factors most relevant to this rejection are the scope of the claim, the amount of direction or guidance provided, the lack of sufficient working examples, the unpredictability in the art and the amount of experimentation required to enable one of skill in the art to practice the claimed invention.

At issue is whether or not the claimed composition would function as therapeutic composition. Although Applicant's specification describes certain in vitro experiments, there is no correlation on this record between in vitro experiments and a practical functional use is currently available form for humans or animals. The US 20020058336 publication teaches that the alpha6/beta1 integrin is expressed on platelets, lymphocytes, monocytes, thymocytes and epithelial cells, on which it functions as a laminin receptor for laminin-1, laminin-2 and laminin-4 *in vivo*. It is also a receptor for laminin-5, but not *in vivo* (see page 3, paragraph 19). Cochlovius *et al* (Modern Drug Discovery, 2003, pages 33-38) teach that in contrast to in vitro models, and partly animal-human xenograft systems, tissue cells *in vivo* seems to express molecules for defense against cellular immune systems as well as against complement. Although these defense mechanisms are still poorly understood, they provide some hints as to why many potential therapeutics perform marvelously *in vitro* but a fairly high portion of them still fail *in vivo*. Thus, it is not clear that reliance on the *in vitro* studies accurately reflects the relative mammal and human efficacy of the claimed therapeutic strategy. The specification does not teach how to extrapolate data obtained from *in vitro* studies to the development of effective *in vivo* mammalian including human therapeutic treatment, commensurate in scope with the claimed invention. Therefore, it is not clear that the skilled artisan could predict the efficacy of the fused or chimeric G3 subdomain by administering to a mammal a therapeutically effective amount of therapeutic composition. Thus in the absence of working examples or detailed guidance in the specification, the intended uses of any therapeutic composition comprising the fused or chimeric G3 subdomain of the laminin-5 $\alpha 3$ are fraught with uncertainties. It is not enough to rely on in vitro studies where, as here, a person having ordinary skill in the art has no basis for perceiving those studies as constituting recognized screening procedures with clear relevance to use in humans or animals. Ex parte Maas, 9 USPQ2d 1746. There must be a rigorous correlation of pharmacological activity between the disclosed *in vitro* use and an *in vivo* use to establish practical therapeutic use.

Further, at issue whether the G3 subdomain linked to a therapeutic moiety such as IL-2 would destroy or neutralize a pathogen. It appears that applicant is using the claimed polypeptide

comprising G3 for target delivery of a drug. The specification fails to provide example wherein the IL-2 can destroy or neutralize any pathogen. The skilled artisan would not expect IL-2, a hormone-like substance released by stimulated T lymphocytes, causes activation and differentiation of other T lymphocytes independently of antigen to function in destroying or neutralizing any pathogen. However, in view of the absence of a specific and detailed description in Applicant's specification of how to effectively use the polypeptide as claimed, and absence of working examples providing evidence which is reasonably predictive that the claimed composition are effective for in vivo use, and the lack of predictability in the art at the time the invention was made, an undue amount of experimentation would be required to practice the claimed antibodies with a reasonable expectation of success. Kahan states that, at the time of the invention, "no in vitro immune assay predicts or correlates with in vivo immunosuppressive efficacy; hence, there is no surrogate immune parameter as a basis of immunosuppressive efficacy and/or for dose extrapolation from in vitro systems to in vivo conditions" (Curr. Opin. Immuno. 4:553:560, 1992; see entire document, particularly page 558, column 2) making the in vivo efficacy of an immunosuppressive compound tested solely in vitro unpredictable.

Also, claim 15, recites any "pathogen", it is unclear which patients would be candidates for *in vivo* treatment with a chimeric polypeptide comprising IL-2 and when a patient would be given such treatments/chimeric comprising IL-2. Further, claim 15 recites pathogens comprising at least one of $\alpha 6\beta 1$ integrin receptors and $\alpha 6\beta 4$ integrin receptors on the surface of the pathogen. However, the specification has failed to identify any pathogen (microorganisms) that expresses either $\alpha 6\beta 4$, $\alpha 6\beta 1$ or both integrin receptors. It is noted that $\alpha 6\beta 4$-integrin is predominantly expressed in epithelium and it is a major component of hemidesmosomes that link the cytoskeleton to basement membrane through interaction with laminin-5.

Further, Applicant has not provided sufficient biochemical information that distinctly identifies such "G3 subdomain", "fragment, mutant, homolog, ortholog, analog, or allele" and "at least about 70% sequence identity" other than SEQ ID Nos:2, 4 and 6. While any polypeptide capable of binding to at least one of $\alpha 6\beta 1$ integrin receptor and $\alpha 6\beta 4$ may have some notion of the activity of the "inhibitory agent", claiming biochemical molecules by such properties fails to provide sufficient guidance and direction as to how the skilled artisan can make such "agents", commensurate in scope with the claimed invention. The specification fails to provide any guidance on how to use any chimeric or fusion polypeptide comprising G3 subdomain that can be used to inhibit adhesion and proliferation of a target cell to a substrate. While the specification on pages 30-30 under examples 4 and 5 discloses that the G3 domain of rat laminin-5 $\alpha 3$ chain coated on wells inhibited proliferation of the cancer cells, however, no fusion polypeptide were used to target any pathogen (microorganism).

The term "comprising" in base claim 15 is open-ended. It would leave the claims open for the inclusion of unspecified amino acids at either or both or the N-or C-termini of given sequence even in large amounts. See MPEP 2111.03. Besides the polypeptide comprising G3 subdomain of SEQ ID NO: 6, 4 and 2, there is insufficient guidance as to which amino acid segments within the polypeptide can be unique and retain a distinct functional capability of G3/$\alpha 6$ bearing integrin receptor. Since the amino acid sequence of a polypeptide determined its structural

property, predictability of which amino acid fragment can retain the functional capabilities of the G3/α6 requires knowledge of, and guidance with regard to, which fragments in the polypeptide's sequence contribute to its function.

After a review of the specification with respect to the nature of "fragments" "analogs", "mutants", "homolog", and "alleles", the specification was not found to provide sufficient guidance to the skilled artisan as to how to make and use G3 "analogs", "mutant" , "ortholog", or "allele" commensurate in scope with the instant claims. In particular, it is noted that the specification on page 7 at paragraph 31 discloses that "analog" encompasses "a non-natural molecule substantially similar to either the entire reference protein or polypeptide or a fragment or allelic variant". Further, the specification on page 7, paragraph 32 indicates that "allele" encompasses a naturally-occurring sequence variation relative to the polypeptide sequence of the reference polypeptide. Also, the specification on page 6, paragraph 30, discloses that "homolog" includes polypeptides sequences including one or more substitutions, deletions, or insertions, located at positions of the sequence that do not alter the conformation or folding of the polypeptide. The term "mutant" is defined in the specification on page 6, under paragraph 29 to encompass base changes, deletions, insertions, inversions, translocations, or duplications. "Ortholog" is defined on page 5 of the specification to encompass polypeptide sequence with similar function to polypeptide sequence in an evolutionarily related species. Finally, the term "fragment" is defined on page 5, paragraph 27 of the specification to include an amino acid sequence of that protein that is shorter than the entire protein, but comprising at least about 25 consecutive amino acids of the full polypeptide.

Given the breadth encompassed by the instant claims, Applicant has not provided the skilled artisan with sufficient guidance as to the identity of all residues to be changed, to be left unchanged, to be deleted, or to have additional (unidentified) sequences inserted between. Without clear direction and guidance as to the nature of the changes made to a reference G3 sequence, the skilled artisan would be faced with undue experimentation to produce the immense number of "fragments" "analogs", "mutants", "homolog", and "alleles" encompassed by the instant claims and determine if there were any operative embodiment that would result in the recited functional activity. Thus the specification does not appear to provide the skilled artisan with sufficient guidance to make and use such "fragments" "analogs", "mutants", "homolog", and "alleles", commensurate in scope with the claimed invention of therapeutic composition encompassed by the claims. The specification offers no guidance as to what particular fragment, other than SEQ ID NOs:2, 4, and 6, are required to ensure the inhibition response. A myriad of polypeptide is encompassed by the claims.

It was well known to those skilled in the art at the time the invention was made that minor structural differences among structurally related compounds or compositions can result in substantially different pharmacological activities. For example, Burgess et al (J Cell Biol. 111:2129-2138, 1990) show that a conservative replacement of a single "lysine" reside at position 118 of acidic fibroblast growth factor by "glutamic acid" led to the substantial loss of heparin binding, receptor binding and biological activity of the protein. The references demonstrate that event a single amino acid substitution or what appears to be an inconsequential

chemical modification will often dramatically affect the biological activity and characteristic of a protein.

Also, it is recognized in the art that ligands must posses significant structural and chemical complementarity to their target receptors (Kuntz, Science, 1992, Vol. 257:1078-1082, especially page 10709, 2nd col., lines 1-4 and 9-12 under heading "Structure-Based Design) and that ligands generally bind to native states of proteins with little or no interaction with unfolded states (Miller et al, Protein Science, 1997, 6:2166-2179, especially page 2166, 2nd col., lines 18-20) and further that alterations in protein structure lead to alterations in bindings affinity proportional to the magnitude of the alteration (Miller et al, abstract, lines 2-4). Finally, Kuntz teaches that as little as 2% of compounds predicted to inhibit specific enzymztic or receptor systems actually shown inhibition in the micromolar range (page 1080, 3rd col.). The claims encompass alterations in protein folding because claims do permit deviation from the amino acid sequences of the G3 subdomain of SEQ ID NO: 6 for a non-native protein. It would be reasonable to conclude that alterations in polypeptide folding would lead to a large alteration in binding affinity.

The art acknowledges that function cannot be predicted based solely on structural similarity to a protein found in the sequence databases and recognized that it was unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences. Attwood (Science 2000; 290:471-473) teaches that "[i]t is presumptuous to make functional assignments merely on the basis of some degree of similarity between sequences. Similarly, Skolnick et al. (Trends in Biotech. 2000; 18(1):34-39) teach that the skilled artisan is well aware that assigning functional activities for any particular protein or protein family based upon sequence homology is inaccurate, in part because of the multifunctional nature of proteins (e.g., "Abstract" and "Sequence-based approaches to function prediction", page 34). Even in situations where there is some confidence of a similar overall structure between two proteins, only experimental research can confirm the artisan's best guess as to the function of the structurally related protein (see in particular "Abstract" and Box 2). Thus it is unpredictable if any functional activity will be shared by two polypeptides having less than 100% identity over the full length of their sequences.

Reasonable correlation must exist between the scope of the claims and scope of the enablement set forth. In view on the quantity of experimentation necessary the limited working examples, the nature of the invention, the state of the prior art, the unpredictability of the art and the breadth of the claims, it would take undue trials and errors to practice the claimed invention.

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

*(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.*

15. Claims 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldfinger *et al* (2000, IDS Ref. NO. C15) as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11.

Goldfinger *et al* teach a fused polypeptide comprising G3 (claimed SEQ ID NO: 6) of laminin-5 α3 chain as a first component and six His residues as a second component (see page 34888 1st col., 1st paragraph in particular). The six His residues are considered a polypeptide. It is noted that that the six His residues are covalently (chemical bound) bound to the G3 domain.

The globular domain of the α3 subunit of laminin-5 (LN5) is the claimed SEQID NO: 6 as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11 that G3 subdomain is SEQ ID NO: 6.

While the prior art teachings may be silent as to the "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" per se; the product in the reference is the same as the claimed product. Therefore "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" is considered inherent properties.

Applicant is reminded that when a claim recites using an old composition or structure (e.g. a polypeptide comprises the G3 subdomain) and the use is directed to a result or property of that composition or structure (capable of binding to at least one of α6β1 integrin receptor and α6β4 integrin receptor), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

16. Claims 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Lazarova *et al* (2001) as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11.

Lazarova *et al* teach a fused polypeptide comprising G3 (claimed SEQ ID NO: 6) of laminin-5 α3 chain as a first component and GST (glutathione-S-transferase) as a second component (see abstract and figure 1 in particular). The GST is considered a polypeptide. It is noted that that the GST are covalently (chemical) bound to the G3 domain.

The globular domain of the α3 subunit of laminin-5 (LN5) is the claimed SEQID NO: 6 as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11 that G3 subdomain is SEQ ID NO: 6.

While the prior art teachings may be silent as to the "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" per se; the product in the reference is the same as

the claimed product. Therefore "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" is considered inherent properties.

Applicant is reminded that when a claim recites using an old composition or structure (e.g. a polypeptide comprises the G3 subdomain) and the use is directed to a result or property of that composition or structure (capable of binding to at least one of α6β1 integrin receptor and α6β4 integrin receptor), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

17. Claims 51-52 and 54-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Shang *et al* (2001, IDS Ref. No 17) as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11.

Shang *et al* teach a fused polypeptide comprising G3 (claimed SEQ ID NO: 6) or G1-3 (claimed SEQ ID NO: 4) of laminin-5 α3 chain as a first component and six His residues as a second component (see page 33048 figs. 2 and 3 in particular). The six His residues are considered a polypeptide. It is noted that that the six His residues are covalently (chemical bound) bound to the G3 or G1-3 domain.

The globular domain of the α3 subunit of laminin-5 (LN5) is the claimed SEQID NO: 6 and G1-3 is claimed SEQ ID NO: 4 as is evidenced by the specification on page 10, lines 27-28, and page 11, lines 5-6 and 10-11.

While the prior art teachings may be silent as to the "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" per se; the product in the reference is the same as the claimed product. Therefore "specifically binds to at least one of α6β1 integrin receptor and α6β4 integrin receptor" is considered inherent properties.

Applicant is reminded that when a claim recites using an old composition or structure (e.g. a polypeptide comprises the G3 subdomain) and the use is directed to a result or property of that composition or structure (capable of binding to at least one of α6β1 integrin receptor and α6β4 integrin receptor), then the claim is anticipated. See MPEP 2112.02. Also, see Bristol-Myers Squibb Co. v. Ben Venue Laboratories, Inc. 58 USPQ2d 1508 (CA FC 2001); Ex parte Novitski 26 USPQ 1389 (BPAI 1993); Mehl/Biophile International Corp. V. Milgraum, 52 USPQ2d 1303 (Fed. Cir. 1999); Atlas Powder Co. V. IRECO, 51 USPQ2d 1943 (Fed. Cir. 1999).

The reference teachings anticipate the claimed invention.

18. No claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maher Haddad whose telephone number is (571) 272-0845. The examiner can normally be reached Monday through Friday from 7:30 am to 4:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

April 20, 2005

Maher Haddad

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